510(k) Summary

FEB 2 4 2005

K050223

General Information

Classification	Class II
Trade Name	Coaxial Introducer
Submitter	Vivant Medical, Inc. 1916-A Old Middlefield Way Mountain View, CA 94043 (650) 694-2900
Contact	Kristine Foss Vice President, Regulatory, Quality and Clinical

Intended Use

The VivaWave™ Microwave Ablation System is intended for coagulation of soft tissue. The Coaxial Introducer is intended to aid insertion of the microwave energy applicator component of the system. The system is not intended for use in cardiac procedures.

Predicate Devices

VivaWave™ Microwave Ablation System	K011676

Device Description

The VivaWave™ Microwave Ablation System consists of a microwave power generator and a disposable probe that is the microwave energy applicator. The disposable probe is inserted into soft tissue to coagulate a volume of tissue surrounding the active area of the probe. The Coaxial Introducer may be used to aid insertion of the microwave energy applicator.

Materials

All patient contact materials used in the manufacture of the Coaxial Introducer are suitable for this use and have been used in numerous previously cleared products.

Summary of Substantial Equivalence

The VivaWave Microwave Ablation System with the addition of the Coaxial Introducer is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Vivant Medical believes the Coaxial Introducer is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2005

Ms. Kristine Foss
Vice President, Regulatory, Quality and Clinical
Vivant Medical, Inc.
1916-A Old Middlefield Way
Mountain View, California 94043

Re: K050223
Trade/Device Name: Coaxial Introducer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 28, 2005
Received: February 9, 2005

Dear Ms. Foss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	This application K050223
Device Name:	Coaxial Introducer
Indications for Use:	The VivaWave™ Microwave Ablation System is intended for coagulation of soft tissue. The Coaxial Introducer is intended to aid insertion of the microwave energy applicator component of the system. The system is not intended for use in cardiac procedures.

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050223